STATE MEDICAID P&T COMMITTEE MEETING

THURSDAY, October 20, 2011
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114

MINUTES

Committee Members Present:

Ellie Brownstein, M.D.
Morgan L. Sayler, PharmD.
Lisa Hunt, R.Ph.
Beth Johnson, R.Ph.
Bernadette Kiraly, M.D.
Roger Martenau, M.D.
Jameson Rice, PharmD.

Dept. of Health/Div. of Health Care Financing Staff Present:

Tim Morley, R.Ph.
Robyn Seely, Pharm.D. .

University of Utah Drug Information Center Staff Present:

Melissa Archer, Pharm.D.

Other Individuals Present:

Kim Eggert, Gilead Sciences
Debroah Grafts, Abbott
Mike Broadhead, Abbott
Brooks Hubbard, Boehringer Ingelheim

Meeting conducted by: Ellie Brownstein.

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1 Review and Approval of Minutes: Ellie Brownstein moved to approve the minutes. Lisa Hunt seconded the motion. The motion was approved unanimously.

2 Housekeeping: Ellie Brownstein went over the Pharmacy and Therapeutics Committee goals and responsibilities. The Utah 2007 legislature passed Senate Bill 42 which established Utah Code 26-18-2.4. This language requires the Division of Health Financing to establish a Preferred Drug List (PDL) program to operate within the Utah Medicaid Pharmacy Program and at the Division's discretion. Under this program the Division is directed to establish a Pharmacy and Therapeutics Committee that functions as a professional and technical advisory board to the Division in the formulation of a PDL. The Committee is specifically asked to make recommendations on the safety and efficacy of pharmaceuticals within a therapeutic class of medications being reviewed for potential inclusion on the state's PDL.

Ellie Brownstein then asked Morgan L. Sayler and Jameson Rice to introduce themselves and to tell a little about their work environment so that our committee members will have a chance to get to know her better. Morgan Sayler is our new Acedemic Pharmacist, she

is on faculty at the College of Pharmacy and works at the Greenwood clinic. Jameson Rice is our new Chain Pharmacist who works at Harmons. At the Farmington location and will be moving to the downtown store in Feburary.
Lisa Hunt reminded everyone that there are bagels, smears, coffee, and chocolate covered cranberries and reminded everyone that there is a sign in sheet located at the snack table. She reminded the committee members that the Division looks to them for recommendations on the drug products reviewed at these meetings such as the need for pediatric formulations to be on the Preferred Drug List, or the need for differing dosage forms to be included. Each of the committee members have been recognized as important key individuals within their area of practice and they have been recommended to the Division through their respective professional organizations for this committee.

3 DUR Board Update: Robyn Seely addressed the Committee and reported that at last weeks Drug Utiliztion Review meeting the Board discussed prodrugs and active metabolites. The presentation focused on drugs approved in the last 10 years. Eight drug pairings of pro-drug/active metabolites were covered in detail. It was reported that in recent years, many drugs have been introduced to the market primarily as a means to replace lost revenue associated with the expiration of a drug's patent protection.

Recommendations included: Pro-drugs and active metabolites of existing approved agents be placed on prior authorization unless there is compelling evidence that they are superior to existing agents if the new drug is more expensive to Medicaid than the existing agent. Pro-drugs and active metabolites of existing approved agents will not be placed on prior authorization if they are less costly to Medicaid and they have comparable safety and efficacy. In cases such as Horizant and gabapentin where the new agent is approved for a different indication or indications than the existing drug, prior authorization should be considered for all but the approved indications.

The Board also started to review Xarelto. Dr. Karnick reported that she would appeal to the Board to make this new oral anti-platelet drug easily available to patients upon discharge from the hospital to protect continuity of care. This drug is primarily started in the hospital and continued for 30 to 35 days after discharge. This drug is scheduled for further review at the next DUR Board meeting.

4. Androgenic Agents: Melissa Archer reported on Androgenic agents including fluoxymesterone, methyltestosterone, oxandrolone, and testosterone. She provided a comparison of each of these agents on Table 1. These products are indicated for the treatment of male hypogonadism, delayed puberty, as an adjunct to promote weight gain or offset protein catabolism, and in the palliative treatment of metastatic breast cancer.

Testosterone is the principal secreted androgen in both men and women. A disorder of androgen production in males is termed male hypogonadism and is characterized by a testicular dysfunction resulting in diminished sperm and testosterone production. The consequences of androgen deficiency vary depending on the stage of life and degree of deficiency. Treatment of hypogonadism involves supplementation of testosterone or induction of endogenous testosterone production. Current practice guidelines for androgen replacement recommend androgen replacement therapy with an intramuscular or topical agent but do not recommend a specific product over another. Guidelines recommend serum testosterone concentrations be obtained throughout testosterone therapy to monitor for safety and efficacy.

One meta-analysis and six clinical trials were identified for evaluation. The meta-analysis found all testosterone replacement products were similar in improving erectile dysfunction in hypogonadal men. One small clinical trial found oral androgen replacement was efficacious in improving the progression to puberty in boys aged 12-16. The remaining trials found transdermal, intramuscular, and topical gel testosterone replacement products to be more effective than placebo in improving symptoms in hypogonadal men. Some evidence suggests greater improvements in serum testosterone levels with the Testim® gel product when compared to the Androderm® transdermal patch product.

One meta-analysis of 8 clinical trials demonstrated improvements in lean body mass in patients with HIV wasting syndrome receiving testosterone replacement.

Adverse effects associated with androgen replacement include: acne, gynecomastia, increased sexual aggression, abnormal hematocrit levels, male pattern baldness, worsening sleep apnea, and increased risk of benign prostatic hyperplasia and/or prostate cancer. The oral androgen replacement products are associated gastrointestinal adverse effects and hepatic toxicity. The intramuscular and topical testosterone replacement products are associated with application site reactions. Clinical trials comparing the transdermal product to the gel formulations found higher rates of application site reactions with the transdermal product. Testosterone therapy is not recommended in patients with diagnoses of breast or prostate cancer.

Overall, evidence suggests all androgen replacement products are effective in improving symptoms and can result in improved quality of life. Some evidence suggests increased application site adverse effects with the transdermal patch compared to the topical gel products. Serum testosterone concentrations should be obtained throughout testosterone therapy to monitor for safety and efficacy.

Utilization data was also examined and questions entertained about how the drug is monitored. Blood draws are not routinely done mostly this drug is monitored through symptoms.

The rest of the committee introduced themselves to the new members. Bernadette Kiraly is our Family Practice Medicine representative, Roger Martineau is our Medical Psychiatrist from the Veterans Association, Beth Johnson is our hospital pharmacist, Ellie Brownstein is our Pediatrician and current committee chair, Lisa Hunt is the voting government pharmacist committee member and staffs the committee. Robyn Seely is the Drug Utilization Review Board manager, Melissa Archer works for the University of Utah and is contracted to provide the clinical research for the committee. Utah Medicaid also contracts with the Sovereign States Drug Consortium (SSDC) along with the state Medicaid agencies of Iowa, Maine, Oregon, Vermont, West Virginia, and Wyoming. This allows us a large pool of lives to obtain supplemental rebates for.

Lisa Hunt provided a report on what other (SSDC) states have done with Androgenic Agents.

5. Public Comment: Deborah L. Griffis of Abbott provided testimony on Androgel. The new formulation of Androgel provides 1.62% versus the old product which had a strength of 1%. The pharmacokinetics are different for each of these products. The higher strength allows for a smaller application surface area. The 1.62% is more viscous and the two strengths are not interchangeable.

6. Board Actions: Beth Johnson made a recommendation that the PDL should include a gel and that Prior Authorizations should be considered by the Drug Utilization Review Board.

   Ellie Brownstein made a motion that was seconded by Roger Martenau that these products are equally safe and effective. The motion passed unanimously. Beth Johnson made a motion that was seconded by Ellie Brownstein that the PDL include at least one gel and take into account market share use. This motion was passed unanimously.

   Beth Johnson made a motion that at least one oral formulation needs to be included for patients intolerant to other formulations. This motion was seconded by Ellie Brownstein and passed unanimously.

   Beth Johnson made a recommendation that the Drug Utilization Review Board put an age definition on these products and examine diagnosis and prescriber history of these claims. Refills may also be limited.

Next Meeting Set for Thursday, November 17, 2011
Meeting Adjourned.
Minutes prepared by Lisa Hunt from notes taken at the meeting.